

Claims

1. A recombinant protein that exhibits significant sequence homology with the tick-derived protease inhibitor protein (TdPI) sequence given in Figure 1, an active fragment of said protein or a functional equivalent of said protein.
2. A recombinant protein, protein fragment or functional equivalent according to claim 1, that functions as an inhibitor of tryptase, preferably of human mast cell tryptase.
3. A recombinant protein, protein fragment or functional equivalent according to either of claims 1-2 that contains one or more epitopes that can be used in the development of vaccines that target proteins that exhibit significant sequence homology with TdPI.
- 10 4. A recombinant protein or protein fragment according to claim 1, wherein said sequence homology is defined as 50% or more of the amino acids in the sequence being completely conserved as identical residues if the protein is aligned with the sequence of Figure 1, the alignments being obtained using GCG's bestfit command (gap creation penalty = 2.5; gap extension penalty = 0.5).
- 15 5. A recombinant protein or protein fragment according to claim 4, wherein said sequence homology is 60% or more.
6. A recombinant protein or protein fragment according to claim 5, wherein said sequence homology is 75% or more.
7. A recombinant protein or protein fragment according to any one of claims 1-6
- 20 comprising the TdPI sequence.
8. A recombinant protein derived from a blood-feeding arthropod ectoparasite that inhibits tryptase, or an active fragment of said protein or a functional equivalent of said protein.
9. A recombinant protein, protein fragment or functional equivalent according to claim 8,
- 25 that functions as an inhibitor of tryptase, preferably of human mast cell tryptase.

10. A recombinant protein, protein fragment or functional equivalent according to claim 8 or claim 9 that contains one or more epitopes that can be used in the development of vaccines that target proteins that exhibit significant sequence homology with TdPI.
11. A recombinant protein or protein fragment according to any one of claims 1-10 that
5 inhibits tryptase with a K_i of less than 1×10^{-6} M, preferably less than 1×10^{-7} M, more preferably less than 2×10^{-8} M, most preferably less than 1×10^{-9} M.
12. A recombinant protein, protein fragment or functional equivalent according to any one of the claims 1-11 that inhibits catalytic tryptase activity.
13. A recombinant protein, protein fragment or functional equivalent according to any one
10 of claims 1-12 which inhibits mast cell tryptase, preferably human mast cell tryptase.
14. A recombinant protein, protein fragment or functional equivalent according to any one of the preceding claims, that is derived from a tick.
15. A recombinant protein, protein fragment or functional equivalent according to claim 14, that is derived from the tick *Rhipicephalus appendiculatus*.
- 15 16. A recombinant protein, protein fragment or functional equivalent according to any one of the preceding claims that has been genetically or chemically fused to one or more peptides or polypeptides.
17. A recombinant protein, protein fragment or functional equivalent according to any one of the preceding claims that is bound to a support, such as a resin.
- 20 18. A pharmaceutical composition comprising a recombinant protein, protein fragment or functional equivalent according to any one of claims 1-17, in conjunction with a pharmaceutically-acceptable carrier.
19. A vaccine composition comprising a recombinant protein, protein fragment or functional equivalent according to any one of claims 1-15, optionally in conjunction with
25 an adjuvant.
20. A process for the formulation of a pharmaceutical composition according to claim 19 comprising bringing a recombinant protein, protein fragment or functional equivalent

according to any one of claims 1-15 into association with a pharmaceutically-acceptable carrier.

21. A recombinant protein, protein fragment or functional equivalent according to any one of claims 1 to 15 for use as a pharmaceutical.
- 5 22. A method for the prevention or treatment of a disease in a subject, comprising administering to said subject an effective dose of a composition according to claim 18 or claim 19.
23. A nucleic acid molecule encoding a recombinant protein, protein fragment or functional equivalent according to any one of claims 1-16.
- 10 24. A nucleic acid molecule: having the sequence given in Figure 1; which hybridises with said nucleotide sequence under stringent hybridisation conditions; or which encodes on expression a recombinant protein, protein fragment or functional equivalent as defined in any one of claims 1-16.
25. A vector comprising a nucleic acid according to claim 23 or claim 24.
- 15 26. The vector of claim 25 that is virus-based.
27. A host cell transformed or transfected with the vector of claim 25 or claim 26.
28. A transgenic animal that has been transformed by a nucleic acid molecule according to claim 23 or claim 24.
29. A method of preparing a recombinant protein, protein fragment or functional
20 equivalent according to any one of claims 1 to 16, comprising expressing a vector according to claim 25 or claim 26 in a host cell and culturing said host cell under conditions where said recombinant protein, protein fragment or functional equivalent is expressed, and recovering said recombinant protein, protein fragment or functional equivalent thus produced.
- 25 30. Use of a recombinant protein, protein fragment or functional equivalent according to any one of claims 1-17 for: the detection or quantification of tryptase; for the depletion or removal of tryptase from a food product or from a cell culture; as an anti-tryptase agent; or as an anti-inflammatory drug.

31. Use of a recombinant protein, protein fragment or functional equivalent according to any one of claims 1 to 16 in the manufacture of a medicament for the treatment of inflammation in humans or animals.
32. A method of vaccinating a mammal against a disease, or of treating a mammal suffering from a disease, comprising administering a recombinant protein, protein fragment or functional equivalent according to any one of claims 1 to 16 to a said mammal.
33. Use of a protein or protein fragment selected from the group consisting of bovine colostrum trypsin inhibitor, the rat tissue factor pathway inhibitor (TFPI-2), the Kunitz domain of the tick anticoagulant peptide TAP and the two domains in ornithodorin as a tryptase inhibitor.